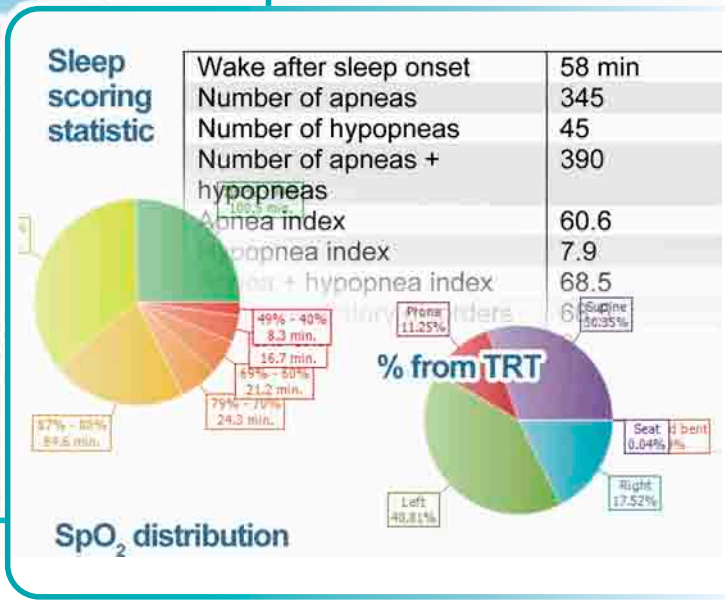
Polysomnograph
for cardiorespiratory sleep disorders analysis

CE 0086

Psychophysiological telemetric system **"Rehacor-T"** with **"Encephalan-PSG"** software for somnological studies



Complies with Type III devices according to AASM classification:
a device for autonomous study with registration at least 4 parameters

AASM — American Academy of Sleep Medicine.

- Airflow
- Respiratory effort
- ECG (or heart rate)
- Oxygen saturation (SpO_2), etc.

bsi. ISO 9001 Quality Management FM 538691

bsi. ISO 13485 Medical Devices Quality Management MD 540857

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Polysomnograph based on the psychophysiological telemetric system "Rehacor-T" provides multichannel registration of various physiological parameters and signals (from 8 to 19 in required combinations) with wireless modules, units and sensors

Basic set of polysomnograph (Basic variant) includes autonomous patient transceiver-recorder ABP-4 (the main amplifier of polysomnograph) and wireless pulse oximeter module.

Complies with Type III devices according to AASM and CSM classification – a device for autonomous (unattended) study with registration at least 4 parameters – the airflow, respiratory effort, heart rate or ECG, oxygen saturation in blood.

Patient transceiver-recorder ABP-4


A_5321

Records parameters via 4 channels and provides data reception and synchronization with other wireless modules.

Modes:

- autonomous (unattended) – data record onto the memory card
- telemetric (attended) – data transmission into computer via wireless Bluetooth channel.

Wireless pulse oximeter module


A_4163

Recorded parameters:

- pressure airflow integrated sensor)
- oxygen saturation in blood (SpO2),
- data on movements and body position (integrated accelerometer movement activity sensor).

Optional wireless modules increase number of recorded parameters

Wireless respiration module


A_4404

Records respiratory parameters via 4 channels

Universal wireless module Poly-4


A_5359

Records polygraphic parameters via 4 channels for advanced cardiorespiatory monitoring and analysis of limbs movement.

Three main variants of polysomnograph:

- **Basic** – cardio-respiratory monitoring.
- **Optimal** – advanced cardiorespiratory monitoring (3 ECG channels) connected to respiratory disorders.
- **Professional** – advanced cardio-respiatory monitoring, registration of limb movements in sleep (restless legs syndrome).

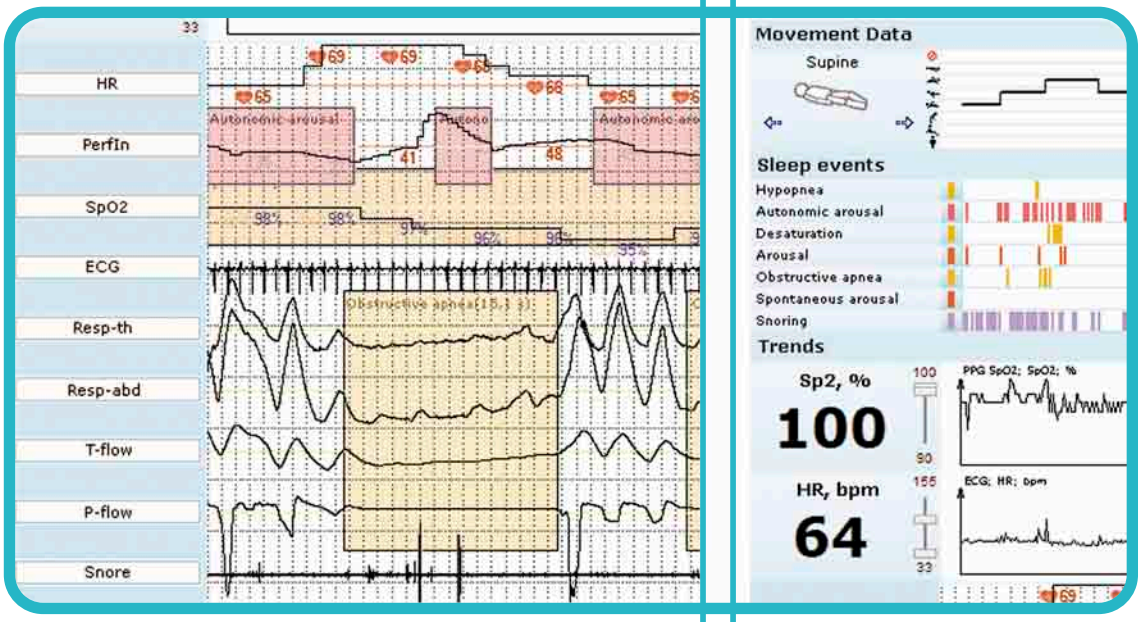
Compliance of sensors, wireless modules and recorded data

Sensors and electrodes	ABP-4	WPM	POLY-4	WRM	Signals and parameters
Pulse oximeter sensor *is connected to wireless pulse oximeter module)*		■			Oxygen saturation
					Photoplethysmogram
					Pulse rate
					Perfusion index
Pressure airflow sensor *(integrated into wireless pulse oximeter module)*		■			Pressure airflow
					Snore *(via cannula of P-flow sensor)*
					Airflow
					CPAP Pressure
Accelerometer movement activity sensor *(integrated into wireless pulse oximeter module)*		■			Movements
					Body position
Respiratory effort sensor *(thoracic and abdominal)*	■			■	Respiratory effort thoracic
					Respiratory effort abdominal
Thermistor airflow sensor	■			■	Temperature airflow
Snore sensor	■			■	Snore
Electrocardiographic sensor	■				Electrocardiogram *(1 derivation)*
Wired limbs movement sensors *(2 pcs.)*	■		■		Motility *(2 channels)*
Electromyographic sensors *(2 pcs.)*			■		Electromyogram *(2 channels)*
PG-ECG connector			■		Electrocardiogram *(3 derivations)*
					Impedance pneumogramm
DC-inputs			■		Data and synchronization signals from other devices

"Encephalan-PSG" software, "basic" suite provides monitoring, recording and analysis of data obtained during PSG study

Main Signal window with signal graphs and automatically searched sleep events marked with colored rectangles.

Trends window containing Movement Data graph, Sleep Events panel and Parameters Trends panel.



Sleep Events panel displays searched events in a compressed form in unified time scale with trends, which allows quickly compare the dynamics of parameters on trends with sleep events to clarify the diagnosis.

- Body movements
- Desaturation
- Critical SpO_2
- Apnea
- Hypoapnea
- Central apnea
- Obstructive apnea
- Mixed apnea
- Cheyne-Stokes respiration
- Airway obstruction
- Limb movements
- Periodic limb movements
- Tachycardia
- Bradycardia
- Extrasystole
- Autonomous arousal

Scrolling of the signal, changing of the scale and sweep speed, enabling/disabling of the signal display, setting of sleep events "detectors" and display of each type of sleep events.

Trend is a compressed representation of initial data and various calculated parameters – SpO2, pulse rate, conventional respiration amplitude, snoring amplitude, etc. Compression ratio (scale of the time axis) can be changed.

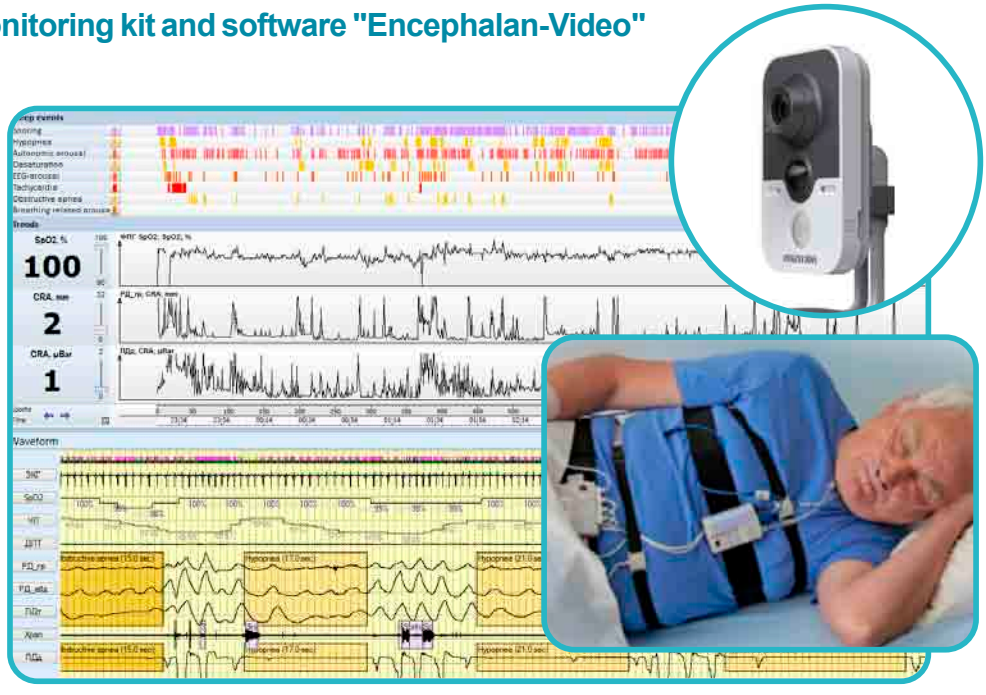
Trends provide quick visual evaluation and comparison of dynamics of parameter changes during continuous record.

Access to required fragment of initial signals for detailed analysis is provided by clicking at any trend point.

Videomonitoring kit and software "Encephalan-Video"

Telemetric mode of polysomnograph (in a hospital ward or at home with data transmission to a doctor's PC via wireless Bluetooth channel) provides continuous over-night PSG video-monitoring with synchronous record of physiological indices in order to compare the clinical manifestations of sleep disorders and identify the connection of respiratory disorders with body position and limb movements.

To be viewed on any computer, study results can be recorded onto external memory devices (DVD, USB drive) in the form of a data set with a special viewer "Encephalan-EEG-Viewer" or as a simple video clip in *.avi format.



Connecting CPAP machines

When connecting an airflow sensor and CPAP-machine via T-adapter to the wireless pulseoximeter module, the polysomnogram records the pressure from the CPAP-machine simultaneously with PSG data for effective selection of CPAP therapy mode.

Reports on PSG-studies

Reports are generated in accordance with detected sleep events. Sleep statistical parameters in these reports are grouped into the following reporting forms:

Sleep structure
- Sleep Scoring Data
- Body positions statistics

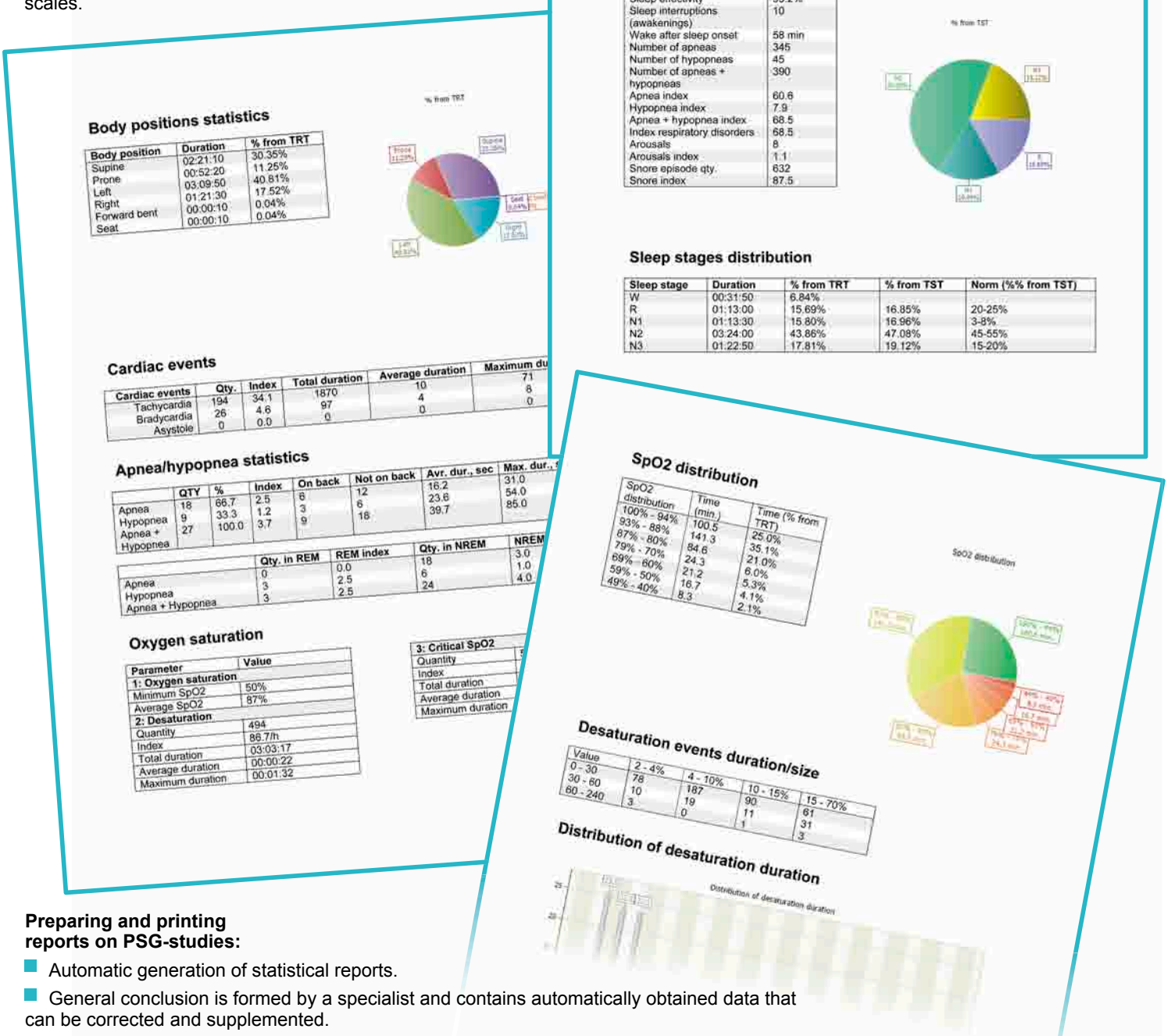
Respiratory disorders
- Apnea statistics
- SpO2 statistics

Cardiogram
- HR statistics

Limb movements
- Periodic limb movements statistics

The report includes the following screen form:

- **Diagrams** – trends of calculated parameters.
- **Sleep events** – list of events and their markers on the time scales.



Conclusion

Obstructive sleep apnea syndrome was severe. AHI = 68.5/h (N<5). Total number of respiratory events – 390, of which obstructive apneas – 345, mixed apneas – 0, central apneas – 0, hypopneas – 45. Maximum duration of obstructive apnea – 126 s. Minimum SpO2 level – 50% (N>90%). Mean SpO2 was low - 86.6% (N>92%). Sleep onset latency was increased - 18 min (N 6–10 min). Sleep efficiency is normal - 93.2% (N>90%). Stage N1 duration increased - 17.0% (N 3-8%). Stage N2 duration is normal - 47.1% (N 45–55%). Stage duration is normal N3 - 19.1% (N 15-20%). Stage REM duration reduced - 16.8% (N 20-25%). Arousals index – 1.1/h (N<21). Most arousals were related to respiratory events.

Sleep Scoring Data

Parameter	Value
Study date	August 12, 2015
Lights out	04:47
Lights on	12:32
Total recording time (TRT)	07:45
Total sleep time (TST)	07:13
Sleep onset	05:01
Sleep latency	14 min
Stage N1 latency	14 min
Stage N2 latency	18 min
Stage N3 latency	26 min
Stage R latency	118 min
Sleep effectivity	93.2%
Sleep interruptions (awakenings)	10
Wake after sleep onset	58 min
Number of apneas	345
Number of hypopneas	45
Number of apneas + hypopneas	390
Apnea index	60.6
Hypopnea index	7.9
Apnea + hypopnea index	68.5
Index respiratory disorders	68.5
Arousals	8
Arousals index	1.1
Snore episode qty.	632
Snore index	87.5

Sleep stages distribution

Sleep stage	Duration	% from TRT	% from TST	Norm (%% from TST)
W	00:31:50	6.84%		
R	01:13:00	15.69%	16.85%	20-25%
N1	01:13:30	15.80%	16.96%	3-8%
N2	03:24:00	43.86%	47.08%	45-55%
N3	01:22:50	17.81%	19.12%	15-20%

Body positions statistics

Body position	Duration	% from TRT
Supine	02:21:10	30.35%
Prone	00:52:20	11.25%
Left	03:09:50	40.81%
Right	01:21:30	17.52%
Forward bent	00:00:10	0.04%
Seat	00:00:10	0.04%

Cardiac events

Cardiac events	Qty.	Index	Total duration	Average duration	Maximum du
Tachycardia	194	34.1	1870	10	71
Bradycardia	26	4.6	97	4	8
Asystole	0	0.0	0	0	0

Apnea/hypopnea statistics

	QTY	%	Index	On back	Not on back	Avr. dur., sec	Max. dur.,
Apnea	18	66.7	2.5	6	12	16.2	31.0
Hypopnea	9	33.3	1.2	3	6	23.6	54.0
Apnea + Hypopnea	27	100.0	3.7	9	18	39.7	85.0

	Qty. in REM	REM index	Qty. in NREM	NREM
Apnea	0	0.0	18	3.0
Hypopnea	3	2.5	6	1.0
Apnea + Hypopnea	3	2.5	24	4.0

Oxygen saturation

Parameter	Value
1: Oxygen saturation	
Minimum SpO2	50%
Average SpO2	87%
2: Desaturation	
Quantity	494
Index	86.7/h
Total duration	03:03:17
Average duration	00:00:22
Maximum duration	00:01:32

3: Critical SpO2	
Quantity	
Index	
Total duration	
Average duration	
Maximum duration	

SpO2 distribution

SpO2 distribution	Time (min.)	Time (% from TRT)
100% - 94%	100.5	25.0%
93% - 88%	141.3	35.1%
87% - 80%	84.6	21.0%
79% - 70%	24.3	6.0%
69% - 60%	21.2	5.3%
59% - 50%	16.7	4.1%
49% - 40%	8.3	2.1%

Desaturation events duration/size

Value	2 - 4%	4 - 10%	10 - 15%	15 - 70%
0 - 30	78	187	90	61
30 - 60	10	19	11	31
60 - 240	3	0	1	3

Distribution of desaturation duration

Preparing and printing reports on PSG-studies:

- Automatic generation of statistical reports.
- General conclusion is formed by a specialist and contains automatically obtained data that can be corrected and supplemented.
- Preparing data for printing using Print Manager.

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